

## **REMARKS**

### **STATUS OF THE CLAIMS**

Claims 17 and 19-23 are pending as shown in the amendment filed with the RCE, received by the Office on April 22, 2004. Applicants note with appreciation that claim 20 remains allowable.

### **REJECTIONS WITHDRAWN**

Applicants acknowledge with appreciation that the previous rejections under 35 U.S.C. § 112, first paragraph, enablement has been withdrawn.

### **35 U.S.C. § 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION**

The sole issue remaining in this case is whether the specification as filed provides adequate written description for claims 17, 19 and 21-23 as required by 35 U.S.C. § 112, first paragraph. In particular, the Examiner maintained that the specification does not adequately describe mutations other than that at position 160 for alphaviruses other than SIN. *See*, Office Action mailed June 3, 2004, paragraphs 12-14.

The fundamental factual inquiry in written description is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. Determining whether the written description requirement is satisfied is a question of fact and the burden is on the Examiner to provide evidence as to why a skilled artisan would not have recognized that the applicant was in possession of claimed invention at the time of filing. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Wertheim*, 191 USPQ 90 (CCPA 1976). It is not necessary that the application describe the claimed invention *in ipsius verba*. Rather, all that is required is that the specification reasonably convey possession of the invention. *See, e.g., In re Lukach*, 169 USPQ 795, 796 (CCPA 1971). Finally, determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by the skilled artisan at the time of filing, for

example as established by reference to patents and publications available to the public prior to the filing date of the application. *See, e.g., In re Lange*, 209 USPQ 288 (CCPA 1981).

Furthermore, the Patent Office's own guidelines on written description are clear -- the written description requirement is highly fact-dependent and there is a strong presumption that an adequate written description of the claimed invention is present at the time of filing:

[t]he description need only describe in detail that which is new or not conventional. This is equally true whether the claimed invention is a product or a process. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that the applicant was in possession of the claimed invention, i.e. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with known or disclosed correlation between function and structure, or some combination of such characteristics. (Final Examiner Guidelines on Written Description, 66 Fed. Reg. 1099, emphasis added).

Simply put, there is absolutely **no** requirement that Applicants exemplify alphavirus particles from each and every alphavirus species falling within the scope of the claims in order to adequately describe the claimed subject matter. Rather, the test is whether the specification, read in light of the state of the art, contains sufficient disclosure regarding the claimed molecules to satisfy the written description requirement.

Applying the applicable rules and case law to the case at hand, it is clear that the specification clearly describes the claimed molecules with respect to any alphavirus (e.g., page 5, lines 4 to 10, and page 21, line 5 to 19, emphasis added):

Within certain embodiments of the above, the alphavirus or recombinant alphavirus particle that **has an amino acid substitution in the E2 glycoprotein as compared to wild-type, for example, at residue 158, 159, 160, 161, or, 162.** Within preferred embodiments, the amino acid substitution is at E2 residue 160. Within other embodiments, the alphavirus has an amino acid deletion or insertion in the E2 glycoprotein. **Within further embodiments, the alphavirus is a Semliki Forest virus, a Ross River virus, a Venezuelan equine encephalitis virus, a Sindbis virus, or ATCC No. VR-2643. ...**

Representative examples of suitable alphaviruses include Aura virus (ATCC VR-368), Bebaru virus (ATCC VR-600, ATCC VR-1240), Cabassou virus (ATCC VR-922), Chikungunya virus (ATCC VR-64, ATCC VR-1241), Eastern equine encephalomyelitis virus (ATCC VR-65, ATCC VR-1242), Fort Morgan virus (ATCC VR-924), Getah virus (ATCC VR-369, ATCC VR-1243),

Kyzylagach virus (ATCC VR-927), Mayaro virus (ATCC VR-66, ATCC VR-1277), Middleburg virus (ATCC VR-370), Mucambo virus (ATCC VR-580, ATCC VR-1244), Ndumu virus (ATCC VR-371), Pixuna virus (ATCC VR-372, ATCC VR-1245), Ross River virus (ATCC VR-373, ATCC VR-1246), Semliki Forest virus (ATCC VR-67, ATCC VR-1247), Sindbis virus (ATCC VR-68, ATCC VR-1248; see also CMCC #4640, described below), Tonate virus (ATCC VR-925), Trinita virus (ATCC VR-469), Una virus (ATCC VR-374), Venezuelan equine encephalomyelitis virus (ATCC VR-69, ATCC VR-923, ATCC VR-1250 ATCC VR-1249, ATCC VR-532), Western equine encephalomyelitis virus (ATCC VR-70, ATCC VR-1251, ATCC VR-622, ATCC VR-125-1), Whataroa virus (ATCC VR-926), and Y-62-33 virus (ATCC VR-375).

Simply put, the specification, including the above passages and Background section, more than adequately describes various alphaviruses and that amino acid residues corresponding to residues amino acids 158-162 of E2 (as numbered relative to wild-type SIN) of any alphavirus were known. Accordingly, one of skill in the art would have known from the specification's teachings that Applicants were in possession of the claimed molecules at the time of filing with respect to multiple alphavirus species.

The Examiner appears to believe that an adequate description is measured solely by what is exemplified (in this case, DC-tropic molecules derived from the prototypical alphavirus Sindbis). However, it is axiomatic that working examples are never required for description and that satisfaction of the written description requirement is determined by what the specification reasonably conveys to the skilled artisan. Thus, the flexibility and wide applicability of the claimed compositions should not be used as a basis for asserting that they are incompletely described; and any requirement for Applicants to actually exemplify alphaviruses other than SIN is both unnecessary for compliance with written description requirements and would prevent them from claiming what they believe to be their invention. Indeed, for the reasons noted above, the skilled artisan, in view of the teachings of the specification, would have known that Applicants were in possession of the claimed subject matter for any alphavirus at the time of filing.

Applicants also note that the DC tropism (functional language) properly adds a further limitation to the claims that must be considered. Functional limitations must be considered. *See, e.g.,* M.P.E.P § 2173.05(g) Functional Limitations, Eighth Edition. In the pending case, the specification as filed clearly describes DC tropism.

Finally, Applicants submit that the Office's reliance on the *Regents of the Univ. Calif. v. Eli Lilly* is misplaced. The written description requirement of section 112 is highly fact dependent and the claims, disclosure and state of the art in *Eli Lilly* is entirely different from those in the case at hand. The holding of *Eli Lilly* is not that a genus can never be described by a single (or a few) representative species, but, instead, that possession of a species can indeed describe possession of a genus if, as in the pending case, the specification adequately describes the structural and functional limitations of the claimed biomolecules to one of skill in the art. Again, Applicants' disclosure includes sufficient structure and functional description to satisfy this requirement. Accordingly, the case cited by the Office is not relevant to case at hand.

Thus, the specification, when properly considered, provides adequate written description for the claimed subject matter, and Applicants request that the rejection be withdrawn.

**CONCLUSION**


Applicants respectfully submit that the claims are in condition for allowance. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

Please direct further communication regarding this application to:

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